

EXHIBIT 2

GIDEON, COOPER & ESSARY
A PROFESSIONAL LIMITED LIABILITY COMPANY

315 DEADERICK STREET, SUITE 1100

NASHVILLE, TENNESSEE 37238

(615) 254-0400

FAX (615) 254-0459

www.gideoncooper.com

C. J. GIDEON, JR.¹
DIXIE W. COOPER²
BRYAN ESSARY³
CHRIS J. TARDIO⁴
CHRISTOPHER A. VRETTOS
ALAN S. BEAN
JAMES C. SPERRING
JOSHUA R. ADKINS
KIM J. KINSLER⁵
RANDA VON KANEL
J. BLAKE CARTER¹
MARK A. HAMMERSVOLD¹
MATT H. CLINE
MATTHEW J. NATHANSON

¹LICENSED IN TN & FL

²LICENSED IN TN, AL & TX

³LICENSED IN TN & GA

⁴LICENSED IN TN & KY

⁵LICENSED IN TN & WI

Matthew H. Cline
Matt@gideoncooper.com

July 21, 2015

Via email only

Michael R. Gottfried
Paul Moore
Duane Morris, LLP
100 High Street
Suite 2400
Boston, MA 02110-1724
mrgottfried@duanemorris.com

Frederick H. Fern
Harris Beach, PLLC
100 Wall Street
23rd Floor
New York, NY 10005
ffern@harrisbeach.com

Re: NECC MDL – Case No. 1:13-md-2419

Dear Counsel:

This letter is our formal request for a meet and confer on the issues outlined below. We are available for a call on July 22, 23, 24, 27, 28, 30, or 31.

As a preliminary matter, I would like to address representations you made to the Court at the May 28, 2015, hearing before Magistrate Boal. Your suggestion to the Court that we have been less than diligent in pursuing documents from NECC is simply untrue. We initially requested access to the documents produced to the PSC by NECC in September 2013. NECC refused us access to them. In January 2014, we, again, requested access to those documents, but, again, NECC refused. We were forced to resort to motion practice in March 2014, at Dkts. 1037 and 1038.¹ Finally, you relented

¹ Our serial attempts at obtaining access to the documents are attached to our brief in support [Dkt. 1038].

and agreed to make available to all parties, including us, "43,000 or 44,000 pages of documents" produced to the PSC.²³

The notion that we have not worked diligently to obtain NECC's documents misrepresents the last two years. We were forced to issue a subpoena to NECC, which is the primary subject of this letter, because it became imminently clear that there remained a significant number of relevant documents being withheld by NECC. Below, I address your objections to our subpoena.

Objections to Document Requests

Request 1: Personnel Files

You objected to our request for personnel files on relevancy grounds. First of all, the personnel files we requested are for individuals who have been indicted. The lone exception is Joseph Connolly, who has been identified in other NECC documents as a technician involved in compounding one or more of the three contaminated lots of MPA. We did not randomly select these individuals. These individuals clearly have at least some involvement in the events at issue. (The criminal indictment relates to the same injuries at issue in the civil cases.) Their personnel files may contain information relevant to a number of different issues.

A few examples:

- One of the allegations pertaining to NECC's fault is a failure to properly train or supervise its employees. Personnel files will likely contain information regarding each employee's position, training, and experience.
- Personnel files may also contain complaints about employee conduct. The pharmacist or technician who compounded the MPA may have been reprimanded previously for failing to maintain proper aseptic technique.
- The personnel files likely contain contact information for former employees that will enable us to locate and contact them.

These are just a few examples of discoverable information that could be in the personnel files.

You also objected to our request for personnel files on confidentiality grounds. There is a robust protective order in place designed to maintain the confidentiality of any sensitive information. Furthermore, if there are specific types of sensitive information or documents you believe to be truly irrelevant (e.g., information regarding an employee's health problems), we are happy to discuss whether it would be appropriate to redact that type of information entirely.

² Hrg Tr. 27:14-29:7 (April 10, 2014 status conference).

³ These documents apparently had long been available to the PSC.

However, it is inconceivable that all of the information and documents in personnel files are either (1) irrelevant or (2) confidential/sensitive. Blanket objections like this, as you know, are roundly disfavored.⁴

Request 4: Customer Files for the Tennessee Clinic Defendants

You objected to our request for customer files for each of our clients on the grounds that our request was too broad for you to conduct a search. At the outset, I will note that we have not yet reviewed the 60,000+ new documents produced by NECC on June 10, purporting to relate to various clinic-related defendants. If the documents sought by this request (or any other request) are included in that production, please identify the document requests to which NECC has now fully responded.

I am not sure how a request specifically targeted to our Tennessee clinics can be too broad. Without knowing anything about how NECC managed its customer accounts, we cannot narrow the request. When we discuss these issues, please be prepared to tell us, generally, how records were maintained for each customer. All we seek are documents specific to our clients. Have searches for Tennessee-related terms been conducted? What terms were used? Would you like us to provide a list of terms? This should not be too difficult.

For example, when we (briefly) toured the facility in July 2014, there were file folders with customer names on them in one part of the building. And, in NECC's internal email traffic, pharmacists or technicians indicate that completed order forms were kept on file. Did NECC do this for all customers? Are there other similar records kept related to specific customers?

Requests 5 and 6: Communications with or about the Tennessee Clinic Defendants

We asked NECC to produce (1) any internal communications or memoranda mentioning our clients and (2) any communications with our clients. Your primary objection to these requests seems to be that they are overbroad. To the extent you are objecting to the lack of time limitation on the request, we are willing to limit the request to 2011 and 2012.

However, if your objection is to the subject-matter of the requests, we may simply need to have Magistrate Boal resolve this issue. Communications with or about our client are clearly relevant and discoverable, and they are likely critical pieces of evidence. I simply do not see how we can narrow these requests beyond limiting it to our clients. Again, if you would like us to provide search terms, just let us know.

⁴ *E.g., Mulero-Abreu v. Puerto Rico Police Dept.*, 675 F. 3d 88, 93 (1st Cir. 2012) ("The plaintiffs' blanket objection to all of the interrogatories—including those asking for basic information—is equally impuissant.") (internal citations omitted).

Request 7: Customer Site Visits or Inspections

We asked NECC to produce documents related to customer site visits or inspections. Your objection seems to request clarification on that point. So, I will do so here. In May 2012, Brigham & Women's Hospital conducted a site visit at NECC. Attached is a report from the audit which was produced by Brigham & Women's, along with a customer survey that appears to have been completed by Barry Cadden in connection with the audit. Similarly, attached is a report from an audit conducted by New York-Presbyterian Hospital in November 2011.

Our request seeks documents relating to those or similar audits. Did any other customers conduct site visits or audits of NECC from 2008-2012? I do not know how much more pointedly we can ask for this critical information. The Plaintiffs claim that our clients should have conducted such an audit. The documents we seek are clearly relevant because they will demonstrate (1) the information NECC would have likely provided our clients during an audit and (2) whether an audit ever led a customer or potential customer to purchase elsewhere.

Request 8: Failure to Comply with USP 797

We requested any internal documents reflecting failure by NECC to comply with USP 797. You responded with the same boiler plate objections included in your other responses. It is unclear to me how this information could *not* be discoverable. One of the major allegations supporting our comparative fault defense as to NECC, is NECC's failure to comply with USP 797. If NECC has internal documents from before the outbreak reflecting NECC's knowledge (or willful concealment) of its failure to comply with USP 797, those documents are certainly discoverable. How could they not be?

Request 9: Patient-Specific Prescriptions

We requested internal documents reflecting training or instruction given to NECC sales people regarding whether patients were required to send patient-specific prescriptions. You objected to this request but actually produced some responsive documents.⁵ These are the types of documents we are looking for. Please let us know whether any similar documents exist and whether NECC will produce them.

Requests 12, 13, and 14: Information about Other Customers or Potential Customers

We requested communications between NECC and customers or potential customers regarding several categories of information (*i.e.*, whether NECC complied with applicable laws, whether NECC had a history of adverse regulatory action, whether NECC had ever been sued for product liability, etc.).⁶ The Plaintiffs allege that our clients should have asked NECC about these topics prior to purchasing. The information NECC gave (or did not give) to other customers regarding these topics will

⁵ See the attached email Bates numbered NECC_MDL000032905.

⁶ Request 12f should say "September 2012" not "September 2011."

help us determine what information, if any, NECC would have given our clients if they had asked. Admittedly, this is information that may be easier to obtain in a deposition of NECC's corporate representative.

Relatedly, we have asked for documents reflecting any due diligence performed by several specific (and well-known) customers of NECC, along with order forms from those customers. Again, these documents will help us establish what our clients would have uncovered if they had conducted similar due diligence. And, we believe that the order forms will show that some of NECC's most well-respected customers did not use patient-specific prescriptions when ordering.

These documents are clearly relevant and discoverable. To the extent you have concerns regarding the confidentiality of records regarding other customers, they may be designated confidential pursuant to the protective order.

Request 16: Cleaning Logs

We requested cleaning logs for Cleanroom 1, and, in response, you produced UniClean's cleaning logs from its monthly cleanings. As you know, both USP 797 and NECC's internal SOPs required additional cleaning beyond UniClean's monthly clean. Please clarify whether any other cleaning logs exist and whether or not they have been or will be produced. If they do not exist or have already been produced, just tell us. Otherwise, the cleaning logs for the cleanroom where the MPA was contaminated are obviously relevant and discoverable.

Request 17: Testing Results

We requested surface and air testing results, and you referred us to some 2012 testing results for Cleanroom 1 that were already produced. First of all, we requested testing results for 2010 to 2012. Please produce all testing results for 2010 and 2011. Second, please confirm that all 2012 testing results for Cleanroom 1 have been produced.

Request 18: Autoclave Records

Similarly, we requested autoclave records for the three contaminated lots of MPA. You referred us to the LFWs that were already produced. Please confirm that no additional autoclave records exist for these three lots.

NECC 30(b)(6) Testimony

I would also like to address your currently pending motion for protective order, which asks the Court to quash the portion of our subpoena that seeks testimony from a corporate representative of NECC. In your motion and during oral argument, you made several representations for which we would like clarification.

At oral argument, you represented to the Court that preparing a corporate representative would be expensive.⁷ This raises several questions that are important to any meet and confer process:

- How much do you estimate it would cost?
- Is this cost already included in the projected \$6 million “Professional Fees” or \$11 million “Trustee Fees” included in the “Liquidation Analysis” at Bankruptcy Dkt. 1309-1? Or, was this cost omitted from the estimate?
- In projecting costs, did the Trustee and his attorneys honestly assume that NECC would never have to present a witness in any of the hundreds of cases pending in the MDL?
- Has NECC made available to the PSC or any other party any NECC principal, employee, or former employee for an informal interview or to give a formal statement? If so, who and when?

Also at oral argument, you represented to the Court that no former NECC employee would consent to testify as its corporate representative.⁸ Please identify the former employees you have approached about serving as corporate representative, including the date they were contacted and their contact information (or their attorney’s contact information).

Documents Produced to Other Parties

You argued, both in your motion and at oral argument, that the 32,000 pages of documents already produced by NECC provided the information necessary to establish our comparative fault defenses.⁹ As of the date of the last hearing, May 28, 2015, just under 33,000 pages from NECC were available on the repository.¹⁰ However, at the April 10, 2014 hearing, when you agreed to make the documents produced to the PSC available to all parties, you stated in open court that NECC had produced “43,000 or 44,000 pages of documents” to the PSC.¹¹

This begs the questions:

What happened to the other ~10,000 pages of documents produced to the PSC, and why were they withheld from us?

⁷ Hr’g Tr. 30:16-31:24 (May 28, 2015 hearing before Magistrate Judge Boal).

⁸ *Id.* at 28:10-21.

⁹ *Id.* at 29:18-30:5; Dkt. 1811 at 11.

¹⁰ See attached log from US Legal dated June 3, 2015 showing the last Bates numbered document produced by NECC to be NECC_MDL000032935.

¹¹ Hr’g Tr. 27:14-29:7 (April 10, 2014 status conference).

Likewise, gaps in the “NECC_MDL” Bates numbering indicate that there are over 1,500 Bates numbered pages missing from the US Legal repository.¹² Presumably, these are documents that were produced to other parties at some point (otherwise, they would not have been Bates numbered).

Why have these documents been withheld?

The inconsistency between the documents and information NECC has made available to the PSC (and others) and to us must end immediately. Please produce every document that has ever been produced to other parties in this litigation or any related case, as you told the Court that you would more than a year ago.¹³ If there are specific documents you are withholding based on a claim of privilege, please produce a privilege log as required by the Federal Rules of Civil Procedure.

Recent Document Productions

Relatedly, at the May 28, 2015 hearing, you represented that NECC had already produced the documents relevant to our comparative fault defenses.¹⁴ Yet, after the hearing, NECC has produced:

- Emails between NECC and UniFirst wherein NECC advised UniFirst that, on two separate occasions *in 2012*, NECC’s environmental monitoring program detected fungus on the same day that UniFirst cleaned the facility.¹⁵ You cannot seriously dispute that (1) these emails are critical to proving the fault of UniFirst and (2) they had not been produced to us as of the May 28, 2015 hearing.
- “Fill logs” documenting when and who filled the vials for the three contaminated lots.¹⁶ As you know, the actual filling of the vials presented an opportunity for contamination of the medication. Identification of the individual responsible for doing so is yet another critical piece of information that was not available to us as of May 28.
- More than 60,000 pages of documents “related to” our clients in response to a June 3, 2015, request from the PSC. We were not copied on the request so we have no way of knowing what the PSC requested. However, the fact that NECC produced the documents, rather than contesting production for lack of relevance, indicates that you believe at least some of them *are* relevant and further undermines Mr. Gottfried’s representations to the Court at the May 28 hearing that we already possess the relevant documents.

¹² E.g., NECC_MDL000030271-31809.

¹³ Hrg Tr. 27:14-29:7 (April 10, 2014 status conference).

¹⁴ Hrg Tr. 29:18-30:5 (May 28, 2015 hearing before Magistrate Judge Boal).

¹⁵ See attached email Bates numbered NECC_MDL000033181.

¹⁶ Oddly, the fill logs have information redacted as privileged. Please explain what privilege you contend applies to the redacted portion of the fill logs.

How can we possibly be confident we have the relevant documents from NECC when critical documents continue to trickle out? Further, we know other critical documents exist because they have been inventoried in the criminal case.¹⁷

Next Steps

This is what we propose:

1. Review and consider this letter and gather the additional information we have asked for, so we can have a meaningful meet and confer regarding the subpoena.
2. Produce to us all NECC documents produced to other parties in this litigation or related litigation.¹⁸
3. Produce to us all document requests and your responses to those requests, which presumably identify the categories of documents being produced,¹⁹ so that we have some context for the now 90,000+ documents produced by NECC.^{20 21}

¹⁷ E.g., The FDA's Certified Inventory of Evidence, filed at Dkt. 237-5 in the NECC criminal docket (Case No. 1:14-cr-10363), references multiple CDs and notebooks of training materials that were seized by the government.

¹⁸ To be clear, we are not asking you to produce documents that are legitimately privileged, such as expert reports exchanged in mediation or financial analyses of the Insiders' assets. However, NECC's documents (as opposed to the Trustee or his attorneys' documents) that have been produced to other parties should be produced to all parties.

¹⁹ For example, the PSC presumably sent a request for all NECC SOPs. In response, NECC presumably sent an enclosure letter with the documents that said, basically, "enclosed as Bates ____ to ____ are all NECC SOPs." Please produce these requests and responses.

²⁰ We know from Mr. Gottfried's comments to the Court that there was a "lengthy meet and confer process" about the documents that would be produced. There must be some document reflecting agreement on the documents that would/would not be produced as part of that process, and some sort of enclosure letter transmitting the documents. Hrg Tr. 27:14-22 (April 10, 2014 status conference).

²¹ *Mulero-Abreu*, 675 F. 3d at 94 ("The same flaws mar the plaintiffs' invitation that the defendants sift through documents previously delivered in search of the documents that they requested under Rule 34. At the very least, the defendants were entitled to responses or objections addressed to 'each item or category [of items]' Fed. R. Civ. P. 34(b)(2)(B). The plaintiffs never supplied such an index, suggesting instead that the defendants find the needle in the haystack.") (alterations in original).

As mentioned at the outset, we are available for a meet and confer call to discuss these issues on July 22, 23, 24, 27, 28, 30, or 31. I look forward to your response.

Thank you.

Sincerely,

/s/ Matthew H. Cline
Matthew H. Cline

Enc: Brigham and Women Hospital's 2012 Audit of NECC; New York-Presbyterian Hospital's 2011 Audit of NECC; Emails Bates numbered NECC_MDL000032905 and NECC_MDL000033181; June 3, 2015 document inventory for US Legal repository.

Cc (via email only): Yvonne Puig; Adam Schramek; Marcy Greer; Eric Hoffman; Sarah Kelly; Parks Chastain; Kent Krause; Ashley Geno; Jay Blumberg; Christopher Wolk; Greg Kirby